UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-CV-12257 PBS
THIS DOCUMENT RELATES TO *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR *State of Montana v. Abbott Labs., Inc., et al.* D. Mont. Cause No. CV-02-09-H-DWM	Judge Patti B. Saris

DEFENDANT-SPECIFIC MEMORANDA
IN SUPPORT OF THE MOTIONS TO DISMISS

The following defendants submit the attached Defendant-Specific Memoranda in Support of the Motions to Dismiss: Abbott Laboratories, Inc.; Amgen Inc.; AstraZeneca Pharmaceuticals LP; Baxter Healthcare Corporation and Baxter International Inc.; Bayer Corporation; Boehringer Ingleheim Corp., Ben Venue Laboratories, Inc., and Bedford Laboratories; B. Braun of America Inc.; Dey, Inc.; GlaxoSmithKline; Immunex Corporation; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Pharmacia Corporation and Pharmacia & Upjohn, Inc.; Schering-Plough Corporation; TAP Pharmaceutical Products, Inc.; and Warrick Pharmaceuticals Corporation.

CERTIFICATION PURSUANT TO LOCAL RULE 7.1

Counsel for defendants hereby certify that they have conferred with plaintiffs in a good faith attempt to narrow or resolve the issues presented by these memoranda.

Schering-Plough Corporation
Warrick Pharmaceuticals Corporation

By their attorneys

Brien T. O'Connor (BBO# 546767)
John T. Montgomery (BBO# 352220)
Crystal D. Talley (BBO#633759)
John R. Therien (BBO#651185)
Ropes & Gray
One International Place
Boston, MA 02110
(617) 951-7000

Dated: November 7, 2003

CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2003, I caused a true and correct copy of the Defendant-Specific Memoranda in Support of the Motions to Dismiss to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

John R. Therien

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#1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Laboratories, Inc., et al.*, 02-CV-12086-PBS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

ABBOTT LABORATORIES, INC.'S SEPARATE REPLY IN SUPPORT OF ITS MOTION TO DISMISS MONTANA'S SECOND AMENDED COMPLAINT

I. Montana Agrees That Rebate Claims Must Be Dismissed As To Non-Innovator, Multiple-Source Drugs.

Montana concedes that it cannot state a Best Price rebate claim for Abbott's non-innovator, multiple-source drugs. *See* Pl. Sep. Mem. at 16. This is because drug manufacturers pay rebates for non-innovator, multiple-source drugs equal to 11% of AMP, without reference to Best Price. *See* 42 U.S.C. § 1396r-8(c)(3). Accordingly, all rebate claims should be dismissed as to non-innovator, multiple-source drugs.

Moreover, because Montana does not identify which drugs are non-innovator, multiple-source drugs, this Court should dismiss the rebate claims as to all of the drugs in the Complaint. Montana knows which drugs are rebated as non-innovator, multiple-source drugs. Rules 8(a) and 9(b) require Montana to identify those drugs subject to its rebate claims.

II. The AWP Claims Should Be Dismissed As To Abbott's Multiple-Source Drugs

Montana concedes that its Medicaid program pays for all formulations of a multiple-source drug at a common amount not tied to any individual manufacturer's AWP. Pl. Sep. Mem. at 11. Specifically Montana Medicaid pays for multiple-source drugs having three or more suppliers based on the lowest AWP published by industry compendia. *See id.* Montana does not contend that any of Abbott's multiple-source drugs enumerated in the Complaint have fewer than three suppliers, and this Court therefore may assume that this payment method applies to the Abbott drugs at issue.

Because multiple-source drugs are paid at a common rate not tied to individual AWPs, the analysis of Montana's AWP-based claims is identical to this Court's consideration of similar claims asserted by private plaintiffs in the Amended Master Consolidated Complaint ("AMCC"). This Court has rejected such claims once already. *See In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 n.11 (D. Mass. 2003) (hereinafter "*AWP*

Litigation"). As argued in Abbott's motion to dismiss the AMCC, those claims should be dismissed again. *See* Abbott Sep. Mem. In Support of Motion to Dismiss AMCC at 4.

Specifically, this Court should dismiss claims as to all drugs for which Montana fails to allege the three vital elements of a reimbursement system in which AWP manipulation is possible:

1. A competitive, therapeutic equivalent must exist.
2. The provider who chooses the drug must receive payment directly.
3. The payment for the two competing drugs must be based upon each drug's individual AWP. See 42 C.F.R. § 405.517(b).

Montana satisfies these pleading requirements for none of the Abbott drugs enumerated in the Complaint. Indeed, Montana fails to state whether it pays for *any* of these drugs based on an individual AWP. This criticism of Montana's Complaint is not "silly" as Montana suggests. *See* Pl. Sep. Mem. at 20. Rather it is simply a demand that Montana meet its obligations under Rule 9(b). Because Montana abdicates that responsibility, all of its AWP-based claims should be dismissed.

III. Montana Knew That AWP Exceeded Market Prices

Montana cannot deny that it had actual knowledge of the market price for all Abbott drugs. Specifically, Montana could derive each drug's AMP merely by dividing its rebate payments by 0.11 or by 0.151 (depending upon the category of drug). 42 U.S.C. § 1396r-8(c). AMP, of course is the average price at which retail pharmacies purchase the drugs. *See id* (k)(1). This fact is flatly contrary to Montana's claim of fraud, and requires dismissal.

Unable to refute this fact, Montana responds with irrelevant arguments. First, Montana contends that the allegations in the Complaint control, irrespective of the truth. Pl. Sep. Mem. at 21. Montana forgets, however, that the Court may reject a plaintiff's allegations where, as here,

the law contradicts them. *See Soto-Negron v. Taber Partners I,* 339 F.3d 35, 38 (1st Cir. 2003); *Massachusetts Laborers' Health & Welfare Fund v. Philip Morris, Inc.*, 62 F. Supp. 2d 236, 240 (D. Mass. 1999). Second, Montana argues that AMP does not equal AWP. Pl. Sep. Mem. at 21. This is true, but irrelevant. AMP is a market-based price; AWP is akin to a list price. Montana knew the difference between the two. Third, Montana argues that Abbott cannot assert estoppel against the State. *Id.* Abbott is not asserting estoppel in this motion. Finally, Montana argues that Abbott is asking the State to "make a complicated mathematical sleuthing exercise." *Id.* Dividing by 0.11 or 0.151 is not complicated.[1]

Given Montana's knowledge of market prices, it cannot assert that it was defrauded when AWPs exceeded market prices. Accordingly, the AWP claims should be dismissed.

IV. Montana Does Not Allege A Fraudulent AWP

Contrary to what Montana suggests, it is not enough simply to copy from *Redbook* the AWPs for 300-plus Abbott drugs. This merely establishes that these drugs have an AWP. Montana must explain what is fraudulent about these AWPs. Montana has not done so.

V. Montana Does Not Explain How AWP Manipulation Can Create Competitive Advantage for the Brand Name Abbott Drugs Named in the Complaint

Montana makes no effort to cure the deficiencies in its allegations regarding Abbott's brand name drugs. As noted above, one element of Montana's paradigm case is the existence of a therapeutic equivalent against which AWP-based competition is possible. Because Montana does not identify therapeutic equivalents for Abbott's brand name drugs, its claim should be dismissed.[2]

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[1] Montana's argument that its knowledge regarding Best Price is a jury question is irrelevant. This argument is based on AMP, not Best Price. Moreover, most of the drugs named in the Montana complaint are non-innovator, multiple-source drugs, for which there is no Best Price. *See* 42 U.S.C. § 1396r-8(c)(3).

[2] As described above, Montana also fails to allege the other two elements of its paradigm case as to Abbott's drugs. This requires dismissal as to all Abbott drugs, including the brand name drugs.

Respectfully Submitted,

Dated: November 7, 2003

James R. Daly
JONES DAY
77 West Wacker Drive
Chicago, Illinois 60601
Telephone: (312) 782-3939
Facsimile: (312) 782-8585

R. Christopher Cook
Jesse A. Witten
JONES DAY
51 Louisiana Avenue, N.W.
Washington, DC 20001-2113
Telephone: (202) 879-3939
Facsimile: (202) 626-1700

Counsel for Defendant
Abbott Laboratories, Inc.

#2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs., et al.*, (D. Mont. Cause No. CV-02-09-H-DWM) *State of Nevada v, American Home Products Corp., et al.*, (D. Nev. Cause No. CV-N-02-0202-ECR)	

DEFENDANT AMGEN INC.'S REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS INDIVIDUAL MOTIONS TO DISMISS AMENDED COMPLAINTS FILED BY MONTANA AND NEVADA

Frank A. Libby, Jr.
Kelly, Libby & Hoopes, P.C.
175 Federal Street, 14th Floor
Boston, Massachusetts 02110
Telephone: (617) 338-9300
Facsimile: (617) 338-9911

Joseph H. Young
Steven F. Barley
Hogan & Hartson L.L.P.
111 S. Calvert St., Suite 1600
Baltimore, Maryland 21202
Telephone: (410) 659-2700
Facsimile: (410) 539-6981

The States' opposition to Amgen's motion borrows wholesale from the private plaintiffs' memorandum in opposition to Amgen's motion to dismiss the Amended Master Consolidated Complaint (the "AMCC"), parading the same arguments in support of the assertion that an adequate factual basis for their claims against Amgen can be "inferred" based upon allegations against others. This is precisely the kind of "guilt by association" that the Court has made clear is no substitute for Rule 9(b).[1]

As to Amgen, the States cannot: point to the existence of any government investigation or audit involving AWP; identify a single allegedly fraudulent "spread" or any example of how Amgen supposedly marketed a spread; point to any internal or other documents evidencing or describing any improper pricing or marketing practice by Amgen; or provide even a single example of any allegedly unlawful sales and marketing practice. Instead, they seek to proceed with a breathtakingly broad case involving serious allegations of misconduct, armed with nothing more than generalized allegations of wrongdoing against an entire industry and the assertion that Amgen operates competitively within that industry.

At the September 18, 2003 hearing, the Court specifically rejected such pleading "by association" as an appropriate means of satisfying Rule 9(b), admonishing counsel that plaintiffs cannot simply identify a defendant as a drug company, and from that, conclude that the company must have been involved in the unlawful manipulation of AWP. And yet, that is all the States have done here. They do not provide any specifics in support of their contention that Amgen engaged in

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[1] In fact, the only substantive difference between the States' opposition and the plaintiffs' memorandum filed in support of the AMCC is the States' apparent abandonment of the argument that they should be allowed discovery. As Amgen previously noted, Amgen has not been the subject of a government investigation or audit or Congressional inquiry and, therefore, has not produced documents in these proceedings. Plainly, and as the States appear to acknowledge, this fact does not entitle them to conduct discovery in an effort to find support for their claims. *See, e.g., Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 878 (1st Cir. 1991); *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 39, 46 (D. Mass. 2001).

wrongful conduct. Instead, the States merely recycle the general description of the "AWP scheme" first introduced in the Master Consolidated Complaint, which the Court has already found lacking. As the Court previously has held, plaintiffs in these cases must at a minimum allege fraud with particularity as to *each* defendant. *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F.Supp.2d 172, 194 (D. Mass. 2003).

The States' claim that Amgen "acknowledged" its supposed involvement in "over-reimbursement as a corporate-wide mechanism to gain market share," by referring to Amgen's recent legal challenge to various rulemaking procedures is, in a word, frivolous. In that case, filed after the States commenced this litigation, Amgen challenged under the Administrative Process Act ("APA") a decision by the U.S. Department of Health and Human Services ("DHHS") to reduce Medicare reimbursement for Amgen's new product, Aranesp®. The district court held that Amgen did not have standing to challenge the agency's action under the APA because it was not an intended beneficiary under Medicare. The case (which is outside of the pleadings in any event) can hardly be read to stand for the proposition that Amgen engaged in, much less acknowledged its involvement in, the unlawful manipulation of AWP, as the States suggest.

The States reliance on a "1993 OIG Report" is similarly unavailing. As Amgen noted in connection with its motion to dismiss the AMCC, that report was prepared in connection with DHHS' consideration more than a decade ago of possible changes to the *statutorily fixed reimbursement rate* for Epogen®. The report had nothing whatsoever to do with AWP-based reimbursement and cannot possibly support the States' claims. The study, moreover, does not suggest that Amgen's rebates were in any way improper. In fact, although the Office of the Inspector General ("OIG") recommended that the Health Care Financing Administration ("HCFA") consider reducing the statutory reimbursement rate to reflect end-of-year rebates,

HCFA rejected that recommendation, even noting "that the elimination of rebates . . . would not result in a change in the manufacturer's price, nor would it serve any program end." OIG A-01-92-00506 (incorrectly cited by plaintiffs as OIG A-01-02-00506).

Nor does the report suggest (let alone conclude, as the States do here) that there was anything inappropriate or nefarious about Amgen's unwillingness to provide sensitive pricing information to DHHS, from which States infer that "disclosure of the rebates would have revealed AWP manipulation." As the report makes clear, the agency was able to obtain information relating to Amgen's profits from other sources, including publicly-filed reports. Moreover, the end-of-year rebates to which the States point as evidence of Amgen's involvement in the so-called AWP scheme were hardly "hidden." As is apparent from the report itself, the discounts were readily discernible from customer invoices. In any event, in light of the government's obvious awareness of these rebates and their effect on pricing and the lack of any investigative interest or followup, far from supporting the inference that the States seek to draw, it is frankly more reasonable to infer the *absence* of any improper manipulation.

Unable to allege any specifics supporting their claims against Amgen, the States are left grasping at straws. Pointing to illogical inferences drawn from the alleged conduct of others, citing to cases that do not come close to supporting their assertions and referring to an inapplicable, decade-old OIG report does not satisfy Rule 9(b) and is certainly no substitute for the requisite specifics necessary to move forward with a case of this magnitude. Amgen should be dismissed from this case with prejudice.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in its initial submission and in the defendants' consolidated memoranda, Amgen requests that the States' amended complaints against it be dismissed with prejudice.

Respectfully submitted,

Frank A. Libby, Jr.
Douglas S. Brooks
Kelly, Libby & Hoopes, P.C.
175 Federal Street, 8th Floor
Boston, Massachusetts 02110
Telephone: (617) 338-9300
Facsimile: (617) 338-9911

Joseph H. Young
Steven F. Barley
Hogan & Hartson L.L.P.
111 S. Calvert St., Suite 1600
Baltimore, Maryland 21202
Telephone: (410) 659-2700
Facsimile: (410) 539-6981

Dated: November 7, 2003

#3

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	
THIS DOCUMENT RELATES TO:	MDL NO. 1456
STATE OF MONTANA v. ABBOTT LABORATORIES, INC. et al., Civil Action No. 02-12084-PBS,	Master File No. 01-CV-12257-PBS
and	Judge Patti B. Saris
STATE OF NEVADA v. AMERICAN HOME PRODUCTS CORP. et al., Civil Action No. 02-12086-PBS	

REPLY MEMORANDUM OF LAW IN SUPPORT OF ASTRAZENECA PHARMACEUTICALS LP'S MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT

AstraZeneca Pharmaceuticals LP ("AstraZeneca")[1] respectfully submits this reply memorandum of law in further support of its motion to dismiss the State of Montana's Second Amended Complaint (Mont. Cplt.) and the State of Nevada's Amended Complaint (Nev. Cplt.) (collectively, "Complaints"). As set forth below, and in AstraZeneca's opening brief and defendants' consolidated briefs, the claims against AstraZeneca should be dismissed in their entirety because (i) the claims are preempted; (ii) plaintiffs fail to state a claim under the statutes asserted; and (iii) plaintiffs' fraud-based claims fail to satisfy the pleading requirements of Rule

[1] Although named as a defendant, Zeneca, Inc. has never been served with the State of Montana's Second Amended Complaint or the State of Nevada's Amended Complaint. The entity identified in these complaints as AstraZeneca US does not exist.

9(b). Alternatively, plaintiffs' claims should be limited to those relating to a single AstraZeneca drug, Zoladex® (goserelin acetate implant).

ARGUMENT

PLAINTIFFS FAIL TO PLEAD THE MAJORITY OF THEIR CLAIMS AGAINST ASTRAZENECA WITH THE PARTICULARITY REQUIRED BY RULE 9(B)

In their opposition to AstraZeneca's individual motion to dismiss, plaintiffs concede that there are no particularized allegations in the Complaints about any drug manufactured by AstraZeneca, other than Zoladex. *See* Plaintiffs' Memorandum in Opposition to Defendant-Specific Memoranda ("Pl. Def. Specific Opp.") at 26-27. Although plaintiffs make the bald assertion that AstraZeneca's allegedly fraudulent conduct is "not limited to Zoladex," plaintiffs fail to cite to a single factual allegation to support this assertion, *see* Pl. Def. Specific Opp. at 27, because the Complaints are devoid of any such allegations. Recognizing this fact, plaintiffs instead argue -- again, without any factual basis -- that "*it is reasonable to infer*" that the conduct alleged with respect to Zoladex occurred with respect to "all listed drugs." *Id.* (emphasis added). Thus, by plaintiffs' own admission, inference and speculation is the only basis for their claims against AstraZeneca relating to drugs other than Zoladex. Rule 9(b) clearly prohibits such vacant pleading.

Moreover, plaintiffs cannot escape the requirements of Rule 9(b) on the ground that they lack relevant information. In fact, plaintiffs concede that, despite having ample opportunities to amend their complaints, they have made no effort to use information within their possession to make particularized allegations supporting their claims of fraud. *See* Pl. Def. Specific Opp. at 10 n.9 ("The States do concede that there are methods one can use to estimate the spread based on information that counsel do have . . . ."). Accordingly, plaintiffs' failure to satisfy Rule 9(b)

requires dismissal of all claims relating to any AstraZeneca drug other than Zoladex – under either an AWP or "best price" theory.[2]

Moreover, even with respect to Zoladex, Plaintiffs fail to support their "best price" claims with anything other than conclusory allegations regarding government investigations. In fact, plaintiffs fail to allege even one fraudulent best price report involving Zoladex. Accordingly, plaintiffs' "best price" claims relating to Zoladex must also be dismissed.

CONCLUSION

For the reasons set forth above, in AstraZeneca's prior submissions on this motion, and in the Consolidated Memorandum and Reply, all claims against AstraZeneca should be dismissed; in the alternative, plaintiffs' claims should be limited to those claims relating to Zoladex®.

Dated: Boston, Massachusetts
November 7, 2003

By: Lucy Fowler

Nicholas C. Theodorou, Esq. (BBO# 496730)
Lucy Fowler, Esq. (BBO# 647929)
FOLEY HOAG, LLP
155 Seaport Boulevard
Boston, MA 02210
(617) 832-1000

D. Scott Wise
Kimberley D. Harris
DAVIS POLK & WARDWELL
450 Lexington Avenue
New York, New York 10017
Tel: (212)450-4000

Attorneys for AstraZeneca Pharmaceuticals LP

[2] For the reasons set forth in defendants' prior briefs and the Consolidated Reply, a mere list of published AWPs and the conclusory allegation that these AWPs are somehow fraudulent does not satisfy Rule 9(b) or this Court's directive that plaintiffs must allege a fraudulent AWP for each drug at issue.

#4

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
THIS DOCUMENT RELATES TO *State of Montana v. Abbott Labs, Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

REPLY MEMORANDUM OF BAXTER HEALTHCARE CORPORATION AND BAXTER INTERNATIONAL INC. IN SUPPORT OF THEIR MOTION TO DISMISS MONTANA'S SECOND AMENDED COMPLAINT

Montana's Second Amended Complaint (the "Complaint") fails to set forth requisite specific allegations of wrongdoing on the part of Baxter.[1] The Complaint thus should be dismissed in its entirety as to Baxter. Alternatively, those Counts related to multi-source drugs should be dismissed as to Baxter.

I. THE ENTIRE COMPLAINT IS DEFICIENT UNDER RULE 9(b).

Montana has not, because it cannot, particularized Baxter's role in the alleged AWP and Best Price violations. Because the associated counts of the Complaint allege fraud, they must satisfy Rule 9(b)'s particularity requirements. *Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985). However, Montana still fails to set forth specific details concerning how Baxter might have violated Montana law through its supposed manipulation of the AWPs and/or Best Prices for those drugs that are part of the case. The "Baxter-specific allegations" (Complaint ¶¶ 296-312) primarily refer to drugs that

[1] The Complaint names both Baxter Healthcare Corporation and Baxter International Inc. as defendants; they are referred to collectively herein as Baxter.

are not part of the case.[2] The paragraph Montana cites as indicative of Baxter's alleged AWP violations quotes from a Baxter document given to sales people to demonstrate how they should *explain* the AWP process *to their customers*. *See* Opposition ("Opp."). at 29 (quoting from, but not citing, Complaint ¶ 302). This is clearly not an example of *deceptive* behavior on the part of Baxter. Another document, which Montana cites as relating to PBMs, concerns a homecare provider, not a PBM. *See* Opp. at 29-30, citing Complaint ¶ 306. These factual misstatements, among others, illustrate Montana's contrived efforts to force Baxter into pre-determined, "all defendants" schemes described in the Complaint. Absent the requisite specificity as to Baxter, the entire Complaint should be dismissed for its failure to state a viable claim as to Baxter.

II. COUNT I AND PORTIONS OF COUNTS II, III, AND IV SHOULD BE DISMISSED AS TO BAXTER'S MULTI-SOURCE DRUGS.

Montana now contends that a multi-source drug argument is "improper on a motion to dismiss because the allegations of the complaints' (*sic*) control." Opp. at 11. This assertion contradicts and ignores this Court's ruling with respect to multi-source drugs in connection with the Master Consolidated Complaint. *See* Court's May 13, 2003 Order at 45, n. 11. Next, Montana concedes, while chiding nearly all defendants for wasting pages of their replies with this contention, that it never intended that its Best Price claims apply to non-innovator, multi-source drugs. Opp. at 16. Yet, the fact that most of the defendants found it necessary to make this argument demonstrates that the Complaint fails to satisfy Rule 9(b)'s particularity requirements with respect to multi-source drugs. As with virtually all the Counts, Montana's use of sweeping language

[2] Paragraph 296 and Appendix A contain lists of the drugs for which relief is sought. Paragraphs 298-312 of the Complaint concern 33 Baxter drugs, only seven of which are listed in ¶ 296 and Appendix A - - dextrose, sodium chloride, Factor VIII (Recombinate), Gammagard S/D, gentamycin, heparin, and travasol - - and all of which are multi-source drugs.

and broad-brush allegations leaves Defendants, and this Court, unclear about exactly what is being alleged as to which Defendant; the very issue Rule 9(b) is meant to address. Nonetheless, unlike the allegations in the Complaint, Montana's concession is clear and all Counts in the Complaint concerning Baxter's multi-source drugs should be dismissed.

CONCLUSION

For the foregoing reasons, as well as those stated in the Consolidated Memoranda and those individual Defendants' memoranda that apply to Baxter, this Court should dismiss Montana's Second Amended Complaint in its entirety as to Baxter. At the very least, Counts I through IV should be dismissed as to Baxter's multi-source drugs.

Respectfully submitted,

Tina D. Reynolds
Merle M. DeLancey, Jr.
Tina D. Reynolds
DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
2101 L St. NW
Washington, DC 20037
Telephone: (202) 785-9700
Facsimile: (202) 887-0689
Counsel for Defendants BAXTER HEALTHCARE CORPORATION and BAXTER INTERNATIONAL, INC.

Tina D. Reynolds for
Peter E. Gelhaar (BBO #188310)
DONNELLY, CONROY & GELHAAR, LLP
One Beacon Street
33rd Floor
Boston, MA 02108
Telephone: (617) 720-2880
Facsimile: (617) 720-3554

#5

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION NO. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENTS RELATES TO: *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM	

BAYER CORPORATION'S SEPARATE REPLY MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS

The arguments raised by the State of Montana ("the State") in its Bayer-specific opposition ("Opposition") fly in the face of the plain terms of the settlement agreements at issue. The State's arguments are without merit and its Amended Complaint ("Complaint") against Bayer should be dismissed.

Although the Complaint broadly challenges the AWP and best price for numerous Bayer drugs, the State acknowledges that for the period preceding the 2001 Settlement, the State released all of its AWP claims relating to the only Bayer products named in the body of its Complaint. Opp. at 33-34. The State points to the fact that the Appendix to the Complaint lists two additional Bayer products – DTIC Dome and Mithracin – but the body of the Complaint makes absolutely no allegation of fraud or other wrongdoing as to these products. Similarly, with respect to best price, the State does not dispute that it has settled all of its best price claims as to Cipro® and Adalat® up to the date of the 2003 Settlement. *See id.* at 34 (setting forth the claims allegedly surviving the 2003 Settlement). All that is left of the State's claims is the theoretical and entirely speculative possibility that Bayer may have engaged in conduct prohibited by the settlements after their effective dates. *Id.* This suggestion too rings hollow, because the State has nowhere alleged that Bayer has failed to comply with the extensive price reporting mechanisms called for by the terms of the 2001 Settlement. With nothing left of the Complaint but this merely speculative possibility – one that is nowhere alleged in the Complaint itself – the Complaint should be dismissed.

***Parens Patriae* Claims.** Despite the broad releases Bayer received in exchange for its settlement commitments, the State now argues that it retained the right to sue and collect under its *parens patriae* authority. Opp. at 34. Plaintiff's argument ignores the broad, general releases in the settlements themselves. For example, the 2001 Settlement released "any civil or administrative monetary claim, action, suit or proceeding the State has or may have under any source of law" and "fully discharge[d] Bayer from any obligation to pay restitution, damages,

and or any fine or penalty to the State[.]" Ex. 1, Part III(2).[1] Similarly, the 2003 Settlement released "any civil or administrative claims for damages or penalties that the state of Montana has or may have" and "fully discharge[d] Bayer from any obligation to pay Medicaid-related restitution, damages, an/or any fine or penalty[.]" Ex. 2, § III(2). Indeed, the only claims not released by the State are specifically enumerated in the agreements and do not include the State's current *parens patriae* claims. *See* Ex. 1, Part III(6); Ex. 2, § III(3).

The State's wholly unsupported assertion that it had no authority to release such *parens patriae* claims is wrong. As a variety of courts have recognized, the State has full authority to settle *parens patriae* claims, which are brought in the name of the State and seek payment to it.[2] The State, through the broad releases to which it agreed, has done just that.

Post-Settlement Claims. Recognizing that its claims are barred for the periods preceding the settlements, the State contends that it should still be permitted to recover for the period since the settlements were entered. Opp. at 34. In so doing, the State ignores the fact that the 2001 Settlement established an elaborate and detailed price disclosure process for *all* Bayer drugs, creating the specific standard now applicable to Bayer and as to which the State has not alleged any breach. *See* Ex. 1, Part III(8). Simply put, the State cannot, consistent with Rules 8 and 9(b), state a claim against Bayer for post-settlement AWP or best price fraud in a generalized, industry-wide action without regard for the specific reporting standards imposed upon Bayer by virtue of the settlements and to which the parties agreed.

Mithracin® and DTIC Dome®. The State also claims that the settlements do not impact its AWP and best price claims against Bayer for Mithracin and DTIC Dome – two Bayer

[1] Unless otherwise indicated, all references to exhibits refer to the exhibits to Bayer's Individual Memorandum in Support of its Motion to Dismiss.

[2] *See Alaska Sport Fishing Ass'n, et al., v. Exxon Corp., et al.*, 34 F.3d 769, 773-74 (9th Cir. 1994) (holding that governments' release of "any and all civil claims" included *parens patriae* claims); *see also State of New York v. Reebok Int'l, Ltd., et al.*, 96 F.3d 44, 48-50 (2nd Cir. 1996) (upholding state settlement of *parens patriae* suit), *In re Compact Disk Minimum Advertised Price Antitrust Litig.*, 2003 U.S. Dist. LEXIS 12663, *22-23 (D. Maine, July 9, 2003) (recognizing that states have the authority to settle and release *parens patriae* claims).

products that are not covered by the settlements. While it is true that the settlements make no mention of Mithracin® or DTIC Dome®, the same is true of the Complaint itself. There is absolutely no mention of Mithracin® or DTIC Dome® anywhere in the body of the Complaint, let alone any allegations of fraudulent conduct.[3] Simply listing the published AWP of the drugs without a single allegation of fraudulent conduct is insufficient to establish "exactly what the fraud is[.]" *In re Pharm. Indus. AWP Litig.*, Tr. of Jan 13, 2003 Hearing on Mot. to Dismiss, at 74; *see* Cmplt., Ex. A.

Cipro® and Adalat®. Finally, to the extent the State is pursuing claims of AWP inflation as to Cipro® and Adalat®, the Complaint is similarly deficient. The State's only allegations as to Cipro® and Adalat® concern the best price conduct that was undisputedly released by the 2003 Settlement and which had nothing to do with AWP inflation. *Compare* Cmplt., ¶¶ 621-27, Ex. 2, § II (F). The State cannot rely on the allegations of AWP fraud as to the drugs actually named in the Complaint (and released by the 2001 Settlement) to obtain standing and satisfy the Court's requirements as to completely different drugs as to which the State itself alleges entirely different conduct. *See In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) (plaintiffs must clearly and concisely state what the fraud is for the drugs they purchased); *Asarco, Inc. v. Kadish,* 490 U.S. 605, 615 (1989) (the doctrine of standing is not a "gaming device" that plaintiffs may surmount merely by aggregating allegations).

In sum, the State has released the majority of the claims set forth in the Complaint through the 2001 and 2003 settlements, and fails to allege a cognizable claim of fraud as to any Bayer drugs that may remain. Bayer should, therefore, be dismissed from this case, with prejudice.

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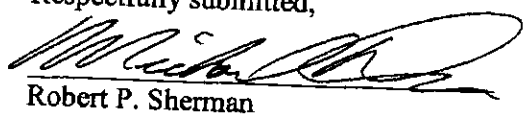
[3] The Complaint does not, in fact, even specifically allege that Plaintiff or its residents purchased the drugs in question. *See* Cmplt., ¶¶ 52, 314. Moreover, to the extent the State's AWP-based claims seek relief concerning Bayer's multiple-source drugs, they must be dismissed for the reasons stated in the Court's May 13 Order. *In Re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d 172, 195 (D. Mass. 2003).

Dated: November 7, 2003

Respectfully submitted,



Robert P. Sherman
NIXON PEABODY
101 Federal Street
Boston, Massachusetts 02110
617-345-6188 (tel.)
866-382-6138 (facsimile)

Richard D. Raskin
Michael P. Doss
Susanna E. Squier
SIDLEY AUSTIN BROWN & WOOD, LLP
10 S. Dearborn Street
Chicago, Illinois 60603
312-853-7000 (tel.)
312-853-7036 (facsimile)

Attorneys for Defendant Bayer Corporation

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